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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/272,835	03/19/1999	FREDERIC J. DE SAUVAGE	PI268R1	6145

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/272,835

Applicant(s)

DE SAUVAGE ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 98-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 98-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.
2. Applicant's arguments filed 1/14/04 have been fully considered but they are not persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 98-102 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, for the reasons made of record in Paper NOs: 10 (mailed 10/27/00), 24 (mailed 7/24/02) and 37 (mailed 10/01/03), and as follows.

Applicants re-iterate their previous arguments and argue that “the specification provides multiple examples of the utility of the claimed nucleic acids, vectors, cells and processes”, and

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cites *E.I. du Pont De Nemours and Co. v. Berkley and Co.*, *Demaco Corp. v. F. Von Langsdorff Licensing Ltd*, and *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.* In contrast to Applicants' assertions, an invitation for others to discover the utility of Applicants' invention by merely providing a laundry list of prophetic utilities does not address the issue as to what "specific" use, or "specific" and assayable function, the instant invention possesses. Nor does the general demonstration of "receptor dimerization" (i.e., a property of many different receptors) address this question of "specific" utility. Nor does a laundry list of prophetic disease states that may be treatable address the question of a "real world" use of the instant invention, in that not a single specific disease state is disclosed within the instant specification to be caused by a dysfunctional GFR $\alpha$ 3 receptor. In other words, how a "GFR *family* of receptors" may, or may not, *generally* function does not address what the claimed unique "GFR $\alpha$ 3" receptor molecules specifically do. Again, as previously made of record, the native ligand of GFR $\alpha$ 3 was unknown at the time of filing the present invention; thereby, preventing one to "assay for *ligand*-induced activity", by definition. Likewise, no specific cell type is described within the instant specification that expresses a *functional* GFR $\alpha$ 3 receptor, if later discovered, or known in the art at the time of filing Applicants' invention. Moreover, nowhere on pages 3, 4, 5, 6, Example 10, Figure 12, or page 56 is a single demonstration of a "single" *specific* use described; thereby, not satisfying the requirements under 35 U.S.C. 101. Accordingly, the court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117, still makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession of *the claimed invention* [emphasis added]", which the current specification clearly does not adequately describe.

As previously made of record, the instant situation is analogous to that decided by the courts in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are “useful” to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of “useful” as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed “real world” utility. In particular, the court held that:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion.”

Therefore, because no known specific biological activity is described within the instant specification nor specifically associated with any nucleic acid that encodes the polypeptides of SEQ ID NO: 17, because the specification merely discloses on page 55 that the human “GFR $\alpha$ 3 does not bind any of these [GDNF family member] molecules (Figure 9C)”, and that “GFR $\alpha$ 3 is thus an orphan receptor”, the claimed polynucleotides have no specific nor substantial utility because further experimentation is also necessary at the time of filing the instant invention to attribute a function and “real world” utility to the claimed nucleic acid molecules.

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5. Claims 98-102 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons made of record in Paper NOs: 10, 24 & 37.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

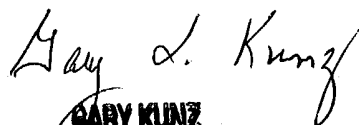
Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
March 24, 2004

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
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